

**REMARKS**

This Amendment is in response to the Examiner's Final Office Action mailed on December 2, 2002. Claims 3, 5, 29, and 31-38 are withdrawn. Claims 2, 15, 39-43 are cancelled. Claims 4, 18, 20-22, and 28 are amended. Claims 1, 4, 6-14, 16-28 and 30 are now pending.

Reconsideration is respectfully requested in view of the above amendments to the claims and following remarks.

**I. Claims Rejections Under 35 U.S.C. § 112, Second Paragraph**

The Examiner rejected claims 1, 4-14, 16-18 under 35 U.S.C. §112, Second Paragraph, for indefiniteness for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

An indefiniteness rejection under 35 U.S.C. §112, Second Paragraph, is based on the objective requirement that claims should be definite to a hypothetical person possessing the ordinary skill in the pertinent art. MPEP 2171.

The Examiner rejected the above claims because "the claim lacks essential steps in the method of treating cancer with a combination therapy." More specifically, the Examiner alleges that the "omitted step is the outcome of the treatment."

Applicant respectfully traverses the Examiner's rejection as improper. According to MPEP 2173.02, the "examiner's focus during examination for compliance with the requirement for definiteness of 35 U.S.C. §112, Second Paragraph, is whether the claims meets the threshold requirement of clarity and precision" not whether the claim omits an essential step. MPEP 2173.02. Rejection of a "claim which omits matter disclosed to be essential to the invention, as described in the specification or in other statements of record may be rejected under 35 U.S.C. §112, First Paragraph," not under §112, Second Paragraph.

However, even if the Examiner made this rejection under §112, First Paragraph, the rejection would be inappropriate, as the outcome of a method of treatment need not be claimed (e.g., amelioration of symptoms) when obvious in light of supporting disclosure. In *Ex parte Skuballa*, 12 USPQ2d 1570 (Bd. Pat. App. & Interl. 1989, the Board held that "a pharmaceutical composition claim which recited an 'effective amount of a compound of claim 1' **without stating the function to be achieved was definite**, particularly when read in light of the supporting disclosure which provided guidelines as to the intended

utilities and how the uses could be effected.” MPEP 2173.05(c) III “Effective Amount,” (emphasis added).

In the present application, Applicant claims a combination therapy in claim 1 which specifies an effective amount of DNA methylation inhibitor in combination with histone deacetylase inhibitor. The application further provides guidelines as to the intended utilities and how the uses could be effected. For example, in the Specification, pages 12-13, Applicants provides guidelines as to the intended utilities (*e.g.*, treating cancer) and how the uses could be effected. Thus, Applicant submits that claim 1 should be sufficiently definite to one of ordinary skill in the art, and respectfully requests that the rejection under 35 U.S.C. 35 U.S.C. §112, Second Paragraph, be withdrawn.

## **II. Claims Rejections Under 35 U.S.C. § 103(a)**

The Examiner rejected claims 1, 4-10, 13, 14, 16-18, 28 and 30 under 35 U.S.C. §103(a) as being unpatentable over Rubinfeld et al. in view of Yang et al.

Applicant respectfully traverses the Examiner’s rejection based on the fact that Rubinfeld et al. cannot be used as 35 U.S.C. §103 prior art because it was commonly owned with the present invention at the time the present invention was made. According to MPEP 2146 “the subject matter developed by another which qualifies as ‘prior art’ only under one or more of subsections 35 U.S.C. §102 (e), (f), and (g) is not to be considered when determining whether an invention sought to be patented is obvious under 35 U.S.C. §103, provided the subject matter and the claimed invention were commonly owned at the time the invention was made.”

Applicants’ patent application was filed on April 24, 2001 whereas Rubinfeld et al. was filed on February 21, 2001. Applicants do not necessarily regard Rubinfeld et al. as prior art of the invention herein. Even if Rubinfeld et al. qualifies as prior art under 35 U.S.C. §102(e), the present patent application and Rubinfeld et al. were commonly owned by SuperGen, Inc. at the time the claimed invention herein was made. For the Examiner’s convenient inspection, Applicants attach hereto a copy of the assignment of Rubinfeld et al. to SuperGen, Inc. Clearly, under 35 U.S.C. §103(c), Rubinfeld et al. cannot be considered in support of an obviousness rejection under 35 U.S.C. §103(a).

For the foregoing reasons, Applicant respectfully requests that the rejection under 35 U.S.C. §103(a) be withdrawn.

**III. Objected Claims**

The Examiner objected to claims 4 and 28 because the claims contained non-elected inventions. In particular, claim 4 contains gallstone which is not a cancer, and claim 28 contains non-elected anti-neoplastic agents, such as alkylating agents.

Applicant amended claims 4 and 28 according to the Examiner's directions. Withdrawal of the objection is therefore respectfully requested.

CONCLUSION

Applicants believe that they are entitled to a letters patent, and respectfully solicit the Examiner to expedite prosecution of this patent to issuance. Should the Examiner have any questions, Examiner is encouraged to telephone the undersigned.

Respectfully submitted,

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